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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/582,863 | 07/06/2000 | David Gustafsson | 3525-86 | 4411 |

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,863

Applicant(s)

GUSTAFSSON, DAVID

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-44 is/are allowed.
- 6) ☒ Claim(s) 20-35, 45 and 50 is/are rejected.
- 7) ☒ Claim(s) 36-40, 46-49 and 51-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 20-57 are pending.

Applicants' amendment filed on October 3, 2003 is acknowledged, and applicants' response has been fully considered. Claims 21-30 and 32-57 have been amended. Thus, claims 20-57 are examined.

Objection Withdrawn

2. The previous objection of claims 21-29, 33-40 and 42-57 is withdrawn in view of applicants' amendment to the claims and applicants' response at page 10 in the amendment filed October 3, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 32-44 and 54-57, under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicants' amendment to the claims and applicants' response at page 11 in the amendment filed October 3, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20-30, 45 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 20 recites the limitation "components (a) and (b)" in line 8. There is insufficient antecedent basis for this limitation in the claim. Claims 21-30 are included in this rejection for

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being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claim 30 is indefinite because the claim recites the kit contains one of components (a) and (b), and the instructions to use that component in conjunction with the other of the two components, it is not clear how to use the two components because the claim only indicate the first component being one component as defined in claim 20, 21, 24 or 27, it does not include the second component, and what the kit is used for.

In response, applicants indicate the kit of parts of claim 30 comprises two things, one of the components and instructions to use that component along with the other, although the kit only includes one component, the instructions would indicate the second component should be included in a method of co-administering with the first (pages 10-11 of the response). The response has been considered, however, the argument is not found persuasive because the claim does not include the second component, how to use the two components, and what the kit for as indicated above.

7. Claims 45 and 50 are indefinite because the claim recites the term “a prodrug of the thrombin inhibitor”, it is not clear which thrombin inhibitor is referred to “the thrombin inhibitor”, is it the first thrombin inhibitor or the second one?

In response, applicants the prodrug is a prodrug of the same thrombin inhibitor (page 11 of the response). The response has been considered, however, the argument is not found persuasive because the claim does not clearly indicate the prodrug is from the same thrombin inhibitor since the independent claim, claim 31 indicates a thrombin inhibitor and a prodrug of a

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thrombin inhibitor in a pharmaceutical formulation, where the two thrombin inhibitors can be different or the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 20, 22, 23, 29 and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Lam *et al.* (U.S. Patent 6,602,871 B2, priority date December 23, 1998).

Lam *et al.* teach nitrogen-containing aromatic heterocycles with ortho-substituted groups such as compounds of formula (I) are useful as factor Xa inhibitors or thrombin inhibitors or pharmaceutical acceptable salts or prodrug thereof, and pharmaceutical compositions comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of at least one of the compounds or a pharmaceutical acceptable salt or prodrug thereof (column 1, lines 39-56; columns 2-8; column 31, lines 29-45; column 47, line 9-column 48, line 57), and these compounds can be administered alone or in combination with one or more additional therapeutic

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agents such as thrombin inhibitors or pharmaceutical acceptable salts or prodrugs thereof (column 48, line 58-column 49, line 62). The compound of formula (I) and one or more therapeutic agents such as thrombin inhibitors or pharmaceutical acceptable salts or prodrugs thereof are administered with a pharmaceutical carrier in pharmaceutical compositions at the same time or sequentially in any order at different time points to provide the desired therapeutic effect for treating thromboembolic disorders such as deep vein thrombosis (column 49, lines 4-62; column 47, lines 9-22; column 50, line 41-column 54, line 4; claims 20, 22, 23, 29, 31-35).

7. Claims 36-40, 46-49 and 51-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Claims 20-35, 45 and 50 are rejected, and claims 36-40, 46-49 and 51-57 are objected to. It appears claims 41-44 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

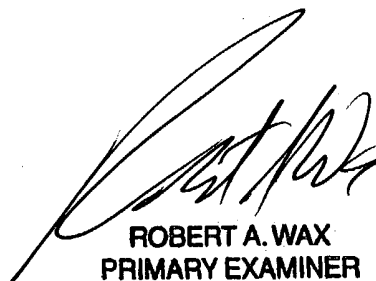
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Chih-Min Kam, Ph. D.
Patent Examiner

CMK

January 13, 2004



ROBERT A. WAX
PRIMARY EXAMINER